

## Forty-ninth Meeting of the Human Tissue Authority

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**Date** 24 May 2011  
**Time** 10.30am – 1.00 pm  
**Venue** The Westminster Conference Centre  
1 Victoria Street  
London, SW1H 0ET

### Agenda

(I) = for information; (D) = for decision

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 22 March 2011 HTA (21/11)
4. Matters arising
5. Chair's report (Committee Membership) Oral
6. ALB review and shared services update (I) HTA (22/11) CEO
7. Update on the implementation of the Organ Donation Directive (I) HTA (23/11) AC
8. Update on post mortem tissue retention in Home Office cases (I) HTA (24/11) AC
9. Post Mortem Sector Report – June 2011 (D) HTA (25/11) AC
10. Living Organ Donation consultation (D) HTA (26/11) AMS
11. Regulatory Activity Report 1 January to 31 March 2011(I) HTA (27/11) AC
12. Summary of post-inspection feedback 2010/11(I) HTA (28/11) AC
13. Absence of a presumed genetic link - update (I) HTA (29/11) AMS
14. Human Tissue Authority public meeting and Annual Review event update (I) HTA (30/11) SG
15. Strategic performance review April 2011 (I) HTA (31/11) AMS
16. Financial report April 2011 (I) HTA (32/11) SM
17. Any other business

## Minutes of the forty eighth meeting of the Human Tissue Authority

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**Date** 22 March 2011

**Venue** The Westminster Conference Centre  
1 Victoria Street  
London  
SW1H 0ET

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### Present

#### Members

Baroness Diana Warwick (Chair)  
Professor Michael Banner  
Mrs Jodi Berg  
Professor Susan Dilly  
Mrs Rosie Glazebrook  
Mrs Pamela Goldberg  
Mrs Suzanne McCarthy  
Professor Gurch Randhawa  
Dr Andrew Reid  
Mr Keith Rigg  
Ms Catharine Seddon

#### In attendance

Mr Craig Muir (Chief Executive)  
Dr Alan Clamp (Director of Compliance and Enforcement)  
Dr Shaun Griffin (Director of Communications and Public Affairs)  
Mrs Sue Martin (Director of Resources)  
Mr Allan Marriott-Smith (Authority Secretary)  
  
Ms Sara Coakley  
(Senior Senior Media and Public Affairs Adviser)  
Ms Laura Nelson  
(Communications Manager)

#### Observers

Mr Patrick Irwin (Department of Health)

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Item	Title	Action
<b>Item 1</b>	<b>Welcome and apologies</b>	
	<ol style="list-style-type: none"> <li>1. Baroness Warwick welcomed Members and observers to the forty-eight meeting of the Human Tissue Authority.</li> <li>2. Apologies had been received from Mr Brian Coulter.</li> </ol>	
<b>Item 2</b>	<b>Declarations of interest</b>	
	<ol style="list-style-type: none"> <li>3. There were no declarations of interest.</li> </ol>	
<b>Item 3</b>	<b>Minutes of 25 January 2011 [paper: HTA (11/11)]</b>	
	<ol style="list-style-type: none"> <li>4. The minutes of 25 January 2011 were adopted subject to one minor amendment.</li> </ol>	
<b>Item 4</b>	<b>Matters arising</b>	
	<ol style="list-style-type: none"> <li>5. The Department of Health (DH) announced formally on 10 March, that the HTA will act as Competent Authority for the Organ Donation Directive. The executive has set up a governance group with DH and NHSBT to develop plans to introduce the Directive by August 2012. Consultation on the content of the regulations will take place between August and October.</li> <li>6. The HTA submitted evidence on presumed consent for organ donation to the Welsh Affairs Committee. The Welsh Assembly Government has now withdrawn the request to the UK government for permission to introduce presumed consent as it believes that following the referendum this permission is no longer required. The HTA will monitor this position and bring further information to the Authority as necessary.</li> </ol>	
<b>Item 5</b>	<b>Chair's report</b>	
	<ol style="list-style-type: none"> <li>7. The Chair informed Members that Pamela Goldberg and Jodi Berg had attended a meeting with the Minister on her behalf. The meeting was positive and the Government's position remains as set out in earlier discussions.</li> <li>8. Member reappointments have been confirmed for Michael Banner, Keith Rigg, Andrew Reid, Catharine Seddon, Jodi Berg, Pamela Goldberg and Brian Coulter. A press notice announcing the reappointments was issued on 22 March. The Chair is still considering refreshes to committee membership and will put proposals to Members at the next Authority meeting.</li> </ol>	

	<p><b>Action: Proposal for committee membership will be brought to the Authority meeting in May.</b></p> <p>9. The Chair invited Craig Muir to provide Members with an update on the structural changes that are taking place within the executive team. The HTA had previously received approval to recruit two Director level posts. The first (Director of Compliance and Enforcement) was filled in January by Alan Clamp, and the second (Director of Strategy and Quality) has now been filled by Allan Marriott-Smith. Craig Muir will end his secondment to the HTA as Chief Executive on 31 May 2011 and the Chair is pursuing a number of avenues to fill this position at the earliest opportunity.</p> <p><b>Action: An organogram setting out the new structure and key responsibilities will be supplied to Members.</b></p> <p>10. The Authority will continue to meet at the Westminster Conference Centre. The July meeting, which will be held in public and combined with the annual review event, will take place in London at a venue yet to be decided.</p> <p>11. The Chair provided Members with an update on a matter which was drawn to their attention at the November meeting. This regarded an investigation of an establishment in the human application sector. This investigation was completed in January 2011 and resulted in the HTA issuing directions to the establishment. The establishment has complied with those directions and the investigation has now been closed.</p>	<p><b>AMS</b></p> <p><b>AMS</b></p>
<b>Item 6</b>	<b>ALB review and shared services update [paper: HTA (12/11)]</b>	
	<p>13. Craig Muir introduced the paper which provided an update on the progress with the ALB review and with the shared services agenda since the last Authority meeting.</p> <p>14. The Authority noted that discussions had taken pace with the CQC at both Chair and Executive level. If the HTA's functions transfer as a whole to the CQC, early thinking on governance arrangements is that oversight of these functions would be undertaken by an advisory board. This board would contain a Member of the CQC board. Members expressed concern that this type of arrangement would undermine the transparent governance and accountability. The HTA should voice this concern as the plans for transition develop.</p>	
<b>Item 7</b>	<b>Statutory approval in cases where directed donation cannot take place [paper: HTA (13/11)]</b>	
	15. Shaun Griffin introduced the paper, which proposed a policy position to adopt for cases where it is discovered that an	

	<p>organ cannot be transplanted to the intended recipient after they have been anaesthetised.</p> <p>16. In discussion, the following points were raised.</p> <ul style="list-style-type: none"> <li>i. Members asked that further work be undertaken on the draft consent form in order to make the options clearer and to meet plain English standards. Gaining consent will also require that the risks of re-implanting are set out.</li> <li>ii. The Authority asked the Executive to explore the possibility that the consent form be accompanied by a patient information leaflet, which is considered good practice where consent is being requested for research.</li> <li>iii. Care should be taken in the tone of communication with surgeons. Keith Rigg offered to provide support to the Executive on this matter and on the development of the consent form.</li> <li>iv. Members expressed some concern that any complexity in the consent form might put potential donors off proceeding. The Executive should consider the best time to communicate these options during the transplant approval process to minimise this risk.</li> <li>v. The Authority noted the legal advice set out in Annex A and agreed that no further legal opinion was needed.</li> </ul> <p>17. The Authority agreed the recommendations set out in the paper subject to the completion of the associated actions.</p> <p><b>Action: The Executive to work with Keith Rigg to finalise the consent form and the communication to surgeons.</b></p>	<p><b>AMS</b></p>
<p><b>Item 8</b></p>	<p><b>Post mortem tissue retention in Home Office cases [paper: HTA (14/11)]</b></p>	
	<p>18. Alan Clamp introduced the paper which had been produced at the Authority’s request in relation to concerns previously expressed by Andrew Reid.</p> <p>19. In discussion, a number of themes emerged:</p> <ul style="list-style-type: none"> <li>i. The Authority expressed two primary concerns relating to the situation described in the paper. First, that gaps in the legislative framework allow poor practice to continue and that steps need to be taken to minimise the impact of these legislative gaps (as a legislative solution is unlikely). Second, that there are potential reputational risks to the HTA of this continued poor practice, even though the HTA’s powers are limited in this area.</li> <li>ii. In relation to gaps in the legislative framework, the approach adopted by the HTA in the past has been to issue advice and guidance to try to minimise the impact of these gaps. While the Authority recognised that the solution proposed in the</li> </ul>	

	<p>paper was a sensible first step, Members also believed that as the proposals have no regulatory or legislative force, other possible solutions should be pursued. In particular, as all Home Office forensic post-mortem examinations are carried out in HTA licensed premises, the Executive should explore whether there is scope to ensure that all parties comply with the relevant legislative requirements as a condition of the license.</p> <p>iii. In relation to concern about the reputational risks to the HTA, the Authority believed there is a need for a very clear explanation of what action should be taken by each party as far as the law is concerned and on the steps being taken by the HTA to rectify the situation.</p> <p><b>Action: The Executive should pursue the recommendations set out in paragraph 12 of the paper and also look in other possible solutions.</b></p> <p><b>Action: The Executive should take steps to minimise the potential reputational risk identified in the discussion.</b></p> <p><b>Action: A paper should be produced for the May meeting updating the Authority on progress.</b></p>	<p>AC</p> <p>AC</p> <p>AC</p>
<b>Item 9</b>	<b>Strategic Plan 2011 to 2014 and Budget and Strategic Performance Review 2011/12 [paper: HTA (15/11)]</b>	
	<p>20. Allan Marriott Smith introduced the paper which presented a near-final draft of the strategic plan for the period 2011 to 2014. Members had made previous contributions to the development of this document at the awayday in September and the November Authority meeting.</p> <p>21. The Authority welcomed the plan and in discussion noted:</p> <p>i. The new KPIs, in particular those which will give an improved picture of issues related to staff retention.</p> <p>ii. The estimated cost of delivering each of the four strategic aims.</p> <p>22. Members approved the plan and the outline budget and noted the efficiency plan and the proposed structure of the strategic performance review.</p>	
<b>Item 10</b>	<b>Communications Strategy 2011-2013 [paper: HTA (16/11)]</b>	
	<p>23. Shaun Griffin introduced the paper, which set out the proposed Communication Strategy for the period 2011 to 2013</p> <p>24. The Authority welcomed the strategy and in discussion:</p> <p>i. Noted the shift in strategic approach towards bringing a sharper focus to public communication with a view to</p>	

	<p>increasing public confidence in the issues within the HTA's remit, but not to increase the profile of the HTA itself.</p> <p>ii. Sought and received assurances that the level of activity set out in the strategy can be achieved once the Communication Directorate is at full strength. If resources cannot be maintained at this level, the plans supporting the strategy can be prioritised.</p> <p>25. The Authority adopted the communications strategy.</p> <p><b>Action: The Executive to regularly report to the Authority on progress in delivering the strategy.</b></p>	<b>SG</b>
<b>Item 11</b>	<b>Strategic Performance Review February 2011 [paper: HTA (17/11)]</b>	
	<p>26. Allan Marriott Smith introduced the paper, a regular agenda item setting out progress against the strategic plan.</p> <p>27. The Authority accepted the paper for information.</p>	
<b>Item 12</b>	<b>Financial report February 2011 [paper: HTA (18/11)]</b>	
	<p>28. Sue Martin introduced the paper which set out the financial position at the end of February 2011</p> <p>29. The Authority was asked to note the underspend, which had resulted from delivering greater efficiency savings than had been envisaged at the start of the financial year. The Authority also noted the intention to return these savings to establishments by way of a credit against 2011/12 licence fees.</p> <p>30. The Authority accepted the paper for information.</p>	
<b>Item 13</b>	<b>Report from the Audit Committee February 2011 [paper: HTA (19/11)]</b>	
	<p>31. Michael Banner introduced the paper which set out the key outcomes of the February Audit Committee.</p> <p>32. The Authority noted that the HTA is to change its internal auditors. The service is likely to be provided through the Department of Health by Grant Thornton. The Committee will meet Grant Thornton on 1 April and confirm the appointment.</p> <p>33. Sue Martin also asked the Authority to note that the interim audit of the end of year accounts by the National Audit Office had been very positive, with only minor issues arising predominantly as a result of new reporting requirements.</p> <p>34. The Authority accepted the paper for information.</p>	
<b>Item 14</b>	<b>Enquiries report December 2010 to February 2011 [paper: HTA (20/11)]</b>	
	<p>35. Shaun Griffin introduced the paper, a regular item setting out the latest report on enquiries received by the HTA.</p>	

	36. In relation to the drop in the number of enquiries, the Executive are exploring whether this is a real change or an issue with under-recording by HTA staff. Further training in enquiries handling is being arranged. 37. The Authority accepted the paper for information.	
<b>Item 15</b>	<b>Any other business</b>	
	38. There was no other business.	

The meeting closed at 1.00 pm



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (22/11)
<b>Agenda item</b>	6	<b>Author</b>	Sue Martin

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## ALB review and shared services update

### Purpose of paper

1. This paper provides the Authority with an update on the latest issues arising from the review of Arm's Length Bodies (ALBs) and developments on the shared services agenda since its last meeting.

### Action

2. The Authority is asked to note the content of the paper and provide any comment.

### Progress in Parliament and elsewhere

3. Since the last Authority meeting in March, the Public Bodies Bill has finished its House of Lords stages. The Human Tissue Authority (HTA) and Human Fertilisation and Embryology Authority (HFEA) were debated in the report stage of the Bill on 28 March, and in the Bill's third reading, which took place on 9 May. The Bill has been returned to the House of Commons for consideration. A summary of the Lords debates is available in the Annex.
4. Earl Howe wrote to Baroness Thornton in response to the report stage debate. In the letter – which has been circulated to Authority members – he noted the Government's intention to consult in late summer on options as to where certain functions are best transferred. In the Third Reading debate he went further saying that having taken into account the strength of feeling expressed during the debates, the Government's preferred option was to transfer the HTA and HFEAs' functions to the Care Quality Commission (CQC), with the exception of certain research-related ones. At present the research functions proposed to

transfer to the new health research regulatory agency are all HFEA functions. None relate to the HTA.

5. The health research regulatory agency will be set up as a special Health Authority this year with the National Research Ethics Service as its core. The aim is to establish the agency as a legal entity in its own right through primary legislation in the second session of this Parliament. Earl Howe gave a commitment on third reading that functions would not be transferred piecemeal but in a single coherent way once the new research regulator had been set up under statute.
6. Earl Howe also said the Government would undertake a full impact assessment. This would include a view about the cost-effectiveness of the Government's proposals where the "key comparison for the purposes of the assessment will be between our preferred option and the organisations' own plans for rationalisation."
7. In summary it would appear that as the Bill passes to the House of Commons, our ambition of keeping all our functions together has gained Governmental support, although we still need to discuss the future of our research functions. This is good news for public confidence in the safe and ethical use of human tissues and organs, and should give greater reassurance regarding the retention of expertise and for the future of HTA staff.

### **Developments with the Care Quality Commission and Department of Health**

8. The Senior Management Team (SMT) met representatives from CQC on 12 May to review developments and discuss plans for working together in areas of potential synergy. They discussed a strategic partnership agreement which would set out the principles of working together and clarify the separate governance and accountability arrangements until such a point as any transfer takes place. The aim is to work on a tripartite basis with HFEA on these areas in future.

### **Shared services**

9. The Department of Health (DH) due diligence exercises (to propose in detail what might be shared by all DH bodies) for finance and HR have taken place. The HTA has just submitted information to an exercise about legal services, where the intention is to reduce the need for legal advice that is not provided by government organisations.
10. On HR, DH has concluded that a shared service model will not realise sufficient savings, although there are benefits in closer working, with larger organisations

each taking a lead on different HR topics and others sharing the resulting service. The HTA is involved in further consideration of this.

11. The finance business case is expected to go to the DH Transformation Board in late May. Subject to comments on the proposals, it is likely to propose the transfer of transactional finance work moves to a shared service between October 2011 and June 2012 and that payroll moves between September 2011 and January 2012. The HTA has not been considered separately to CQC and we are in discussion with CQC about the impact on the HTA.
12. Other work in DH's Business Shared Services Transformation (BSST) programme on estates, procurement and customer services is likely to have little impact on the HTA. Our move to 151 Buckingham Palace Road is in keeping with estates proposals. We increasingly use DH arrangements and other frameworks for procuring goods and services, although these are likely to be mandated in future. Customer services work is to address organisations with high volumes of public enquiries, large numbers of Freedom of Information requests and extensive Ministerial business to manage.
13. DH is exploring scope for sharing communications functions. They recognise the central role of strategic communications as sovereign to organisations. The HTA will be discussing with CQC and HFEA scope for sharing other communications functions (we already use CQC's press cuttings service).
14. The HTA is meeting DH and CQC on 26 May to review progress on sharing services.

## **Annex – Summary of parliamentary debates**

### ***Public Bodies Bill report stage – 28 March***

1. Peers debated two amendments seeking to remove the HTA and the HFEA from the Bill, Diana spoke to these, seeking reassurances from government that our functions would not be split up. Other peers covered issues such as the capability and remit of the CQC to take on our functions, guarantees that the ethical landscape would not be overlooked through any transition thereby eroding public confidence.
2. In response, the minister insisted that the transfer would not be piecemeal and that staff expertise would follow functions, outlined his intention to conduct an impact assessment, envisaged these moves would create savings, and promised consultation. The minister also said he would write to Peers with more detail before the third reading. Opposition spokesperson, Baroness Thornton said she would wait and review the letter to see if it addressed all of her concerns and withdrew the amendments.

### ***Public Bodies Bill third reading stage – 9 May***

3. Peers debated a number of amendments, including three relating to the HTA that Diana was signatory to. They related to changes not being made to the HTA or HFEA's functions without assessment and consultation, and having safeguards in the form of an ethics committee in the new research regulator before any functions are transferred.
4. The debate lasted two hours, during which Diana spoke. The amendments that were voted on were narrowly defeated. The debate proved very helpful in extending and firming up commitments from the minister about the future of the HTA and HFEA. Earl Howe reiterated the point that the transfer of functions would take place at the same time rather than having to go through a series of changes and accepted the case for keeping the HTA functions together. On research, he maintained the distinction between the HTA and the HFEA made in the letter.



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (23/11)
<b>Agenda item</b>	7	<b>Author</b>	Alan Clamp

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## Update on the implementation of the Organ Donation Directive

### Purpose of paper

1. To update the Authority about progress on the implementation of the European Union Organ Donation Directive (ODD) by the Human Tissue Authority (HTA) in its role as the Competent Authority (CA) for all four countries of the United Kingdom.

### Background

2. The ODD requires implementation into UK law by 27 August 2012. The underlying objective of the ODD is to ensure that EU member states introduce a framework for quality and safety in order to maximise the benefits of transplants and minimise the risks. The assurance that each member state is working to the same quality and safety requirements will also facilitate the exchange of organs between member states.
3. Over the next year the HTA will be working with the Department of Health on the drafting of the Regulations that will transpose the Directive into UK law. The HTA will also be developing a set of Directions which will set out the requirements that must be met to ensure compliance with the Directive.

### Key milestones

4. The key milestones for the project are:
  - One-day stakeholder workshop: 19 May 2011
  - Twelve week public consultation on the Regulations and Directions: August to October 2011
  - Revised Regulations and Directions: December 2011

- DI training workshops: January and March 2012
- Regulatory framework in place: March 2012
- Licensing of transplantation activities: April to August 2012
- Implementation of the Directive: 27 August 2012

## **Project status**

5. The project status is currently AMBER.

## **Risk management**

6. It is very positive for the HTA that the organisation has been selected to be the Competent Authority for all four countries of the UK for this important piece of work. It has raised the profile of the HTA and sent out an important message to staff and stakeholders about our continuing functions during these uncertain times. Nonetheless, the timescale for implementation is very tight and there are a number of risks that have to be managed if we are to be successful.
7. The key risks and associated mitigating actions associated with implementing the ODD are outlined below.

**(a) Insufficient staff resource available to carry out the work in the required timeframes.**

This is being mitigated by: recognising the ODD as a high priority project; ring-fencing the time of project team members; reviewing business plan objectives to seek flexibility in timing or scope; making best use of synergies with partner organisations, such as DH and NHSBT; and requesting additional financial resources from DH.

**(b) Regulatory framework is not fit for purpose and/or not deemed to be necessary by the transplant sector.**

This is being mitigated by: regular communication and stakeholder engagement with those involved in the organ donation system; seeking specialist advice on all aspects of the donation process; liaison with the EU and other Competent Authorities; and through the formal public consultation process.

**(c) The deadline for ODD implementation is missed.**

This is being mitigated by: robust project governance and project management; regular reviewing, updating and reporting of project plans; agreement of milestones and deadlines with key partners; ensuring that all partners are aware of the risks and implications of missing the August 2012 deadline for implementation.



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (24/11)
<b>Agenda item</b>	8	<b>Author</b>	Caroline Browne

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## Update on most mortem tissue retention in Home Office cases

### Purpose of paper

1. To inform the Authority of progress made in finding a resolution to the ongoing issue of forensic pathologists retaining tissue that has a bearing on the cause of death under police rather than coronial authority. This relates to ongoing communication problems between pathologists, coroners and establishments that may result in human tissue being retained for longer periods than necessary.

### Background

2. In around 93% of post mortem examinations (PME) conducted annually the need for a PME following a sudden or unexpected death is authorised by a coroner. The coroner instructs a pathologist at a licensed establishment and sets out the expectations for the PME. This is the point at which the first communication problems can arise, as these instructions are often given verbally and practice varies between coroners (**issue 1**).
3. Following the PME, the pathologist will retain tissue if it is relevant to the cause of death and should certify this in writing to the coroner giving reasons for retention. The coroner then authorises the retention and sets the time period for retention. This is the second point at which communication problems can occur (**issue 2**).
4. The coroner then informs the next of kin that the tissue has been retained and seeks their views on the options for the fate of the tissue when the case has been concluded. There is further scope for communication problems during this process in terms of getting the information from the next of kin and passing it on to the pathologist – this is not a requirement under the Coroners Rules (**issue 3**).

5. Once the coroner's interest in the case is concluded s/he should inform the pathologist so that they can arrange to dispose of the tissue in accordance with the wishes of the next of kin. This is another source of communication problems as the coroner does not always notify the pathologist in this way (**issue 4**).
6. The pathologist must record the fate of the tissue but there is no requirement to inform the coroner that the material has been dealt with (**issue 5**).
7. The potential communication problems outlined in paragraphs 2-6 above are further exacerbated by the involvement of the police in around 3% of these cases. The police may seize material (including human tissue) which might have a bearing on a crime *some of which may be relevant to the cause of death*. The Home Office would prefer that all material is seized under police powers, but the coroners feel this would compromise their abilities to fulfil their statutory functions and so want it seized under both sets of powers and this is the current arrangement in most cases. In these cases the PME will be conducted by a Home Office pathologist who should communicate with the coroner in the manner described above.
8. There are clearly some problems in communication between Home Office pathologists and coroners (**issue 6**). These stem from the Section 39 exemption in the HT Act (the licensing requirements relating to removal and storage of tissue do not apply in criminal cases) and a lack of clarity about roles and responsibilities and the jurisdiction issue about under whose authority the material is held. This is further complicated by the fact that only around 30% of cases go to court, at which point the police interest in the other cases may cease but it often not clear about who should then be dealing with the retained tissue.

## Update

9. Following consideration of the paper by Caroline Browne at the 22 March Authority meeting, the following steps have been taken:
  - i. The Home Office's draft guidance document *Legal Issues in Relation to Forensic Pathology and Tissue Retention* has been re-reviewed, to ensure the topic is covered sufficiently and that the guidance it contains is correct. This document will provide much greater clarity for forensic pathologists about their obligations. This should help to address issues **2**, **5** and **6** above.
  - ii. Andrew Reid has posted advice on the Coroners Society (CS) website, setting out the position as he sees it, i.e. that the starting point is Section 20 of the Coroners' Act (CA) 1988 and that under Rule 12 the pathologist must certify in writing to the coroner that material that has a bearing on the cause of death has been retained, and that the coroner is responsible for it from that time on. This should help to address issues **2**, **3**, **4** and **6** above.

- iii. Caroline Browne and Alan Clamp met with Members of the Coroners' Advisory Group (CAG), the Home Office and the National Police Improvement Agency on 9 May 2011 to work out how parties may work together to find a resolution. This meeting served to underline the complexity of the issue, the different perspectives of the parties involved and the different practices of coroners in relation to implementation of Coroners' Rules. Nonetheless, all parties were agreed that greater clarity was needed to promote consistency of practice. The group agreed that a concerted effort was needed to develop a process which everyone should follow. Michael Burgess, HM Coroner for Surrey and a member of the CS Law Committee, has drafted guidance for coroners on how they instruct pathologists, which includes a detailed authorisation form and tissue retention form, which should help to address issues **1**, **2** and **3** above. It was agreed that this might form the basis of joint guidance to be produced.

## Recommendations

10. The following actions are recommended:

- i. Review the CS draft instructions to pathologists and provide comment and suggested amendments to Michael Burgess
- ii. Review the Human Tissue Authority's (HTA) existing communication flowchart to determine how it may be augmented by guidance relating to forensic cases. This should specifically help to address issue **6** above.

11. We have agreed with the CAG that we should aim to sign off both documents at the next Histopathology Working Group meeting in September, at which representatives from all relevant groups will be present. Guidance on best practice would then be circulated to all relevant parties by 30 September 2011. It is hoped that this guidance will reduce and possibly even eliminate some of the communication problems referred to in the PM Sector report to be published in June 2011 and also address many of the problems identified in the recent police audit of retained material. We also need to consider how we might best communicate with the Home Office and coroners where we find deviations from the new process, for example during HTA inspections of licensed premises, in order that the matter can be addressed.

12. In the meantime, if approached for guidance on the issue, we will advise as follows:

- i. Home Office post-mortem examinations are conducted at the request and direction of the coroner under Section 20 of the Coroners Act 1988 and rule

5 of the Coroners Rules. As with any post mortem authorised by the coroner, the pathologist must inform the coroner in writing that material that has a bearing on the cause of death has been retained, and the coroner must, in turn, set a retention period that must not extend beyond the time the case is concluded by Inquest. The coroner also has obligations under the Coroners Rules to inform the next of kin of the disposal options for the tissue when the case is concluded. This means that, for each post mortem conducted under their authority, the coroner should have received from the pathologist a list of tissue samples retained, they should have authorised the retention of these and specified the period for which they should be kept, and they should have notified the next of kin of the tissue that has been retained and explained disposal options. Coroners are reliant on pathologists to provide them with the information about tissue retention, in order that they can fulfill their statutory obligations under Coroners legislation. Coroners should also assist pathologists by informing them that the case has concluded and the tissue can be disposed in the agreed manner.

- ii. On occasion, additional material will be seized by the police under the Police and Criminal Evidence Act (PACE), over and above that which is retained for the coroner's purposes. This material is required by the Police as part of a criminal investigation - the tissue samples are items of evidence and are subject to strict police requirements. Material seized by the Police for determining the criminal liability of a person is not subject to the coroner's authority. Occasionally, tissue will be retained for the coroner's purposes (i.e. to determine the cause of death) as well as for police purposes (i.e. for the detection of a crime or the conduct of a prosecution).
- iii. As all Home Office post-mortem examinations are conducted under the authority of the coroner, material that has a bearing on the cause of death is subject to the requirements of Coroners legislation; any other tissue retention is ancillary to the primary purpose, which is for the Home Office Pathologist to determine the cause of death. The HTA is working with the Home Office and the Coroners Society to develop guidance on Home Office post mortem examinations to ensure greater clarity about roles and responsibilities and greater consistency of practice.

### **Actions for the Authority**

13. Members are asked to note the contents of this report and to approve the recommendations.

**(d) IT systems required for effective implementation are not fit for purpose and/or are not completed on time.**

This is being mitigated by: setting up an IT working group to consider the requirements for licensing, fees and reporting SAEARs; seeking additional funding for the development of IT systems from DH.

**(e) Insufficient funding available to implement the regulatory framework.**

This is being mitigated by: the efficient running of the ODD project; seeking efficiencies by working in partnership with DH and NHSBT; making use of ODD funds held by DH for stakeholder engagement; and making a business case to DH for additional funding.

**Actions for the Authority**

8. Members are asked to note the content of this report.



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (25/11)
<b>Agenda item</b>	9	<b>Author</b>	Alan Clamp

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## Post Mortem Sector Report – June 2011

### Purpose of paper

1. To update the Authority about the Post Mortem (PM) Sector Report due to be published in June 2011.

### Background

2. The first draft of the PM Sector Report was reviewed by the Authority at its meeting in March 2011. It was agreed that the report needed to be tailored more to its target audience(s) and that further work was needed to clarify issues with the data provided by some establishments.
3. The vast majority of the data issues have now been resolved with establishments and the report is now informed by complete data from 197 of the 202 establishments surveyed. The other five establishments are being followed up individually by the HTA.
4. The structure of the report has been amended to provide a front section summarising the high level findings of the report that will be published on the HTA website. A more detailed breakdown of the self-assessment findings, Serious Untoward Incidents and the audit data will be provided as appendices in the version of the report sent to PM establishments.

### The Post Mortem Sector Report

5. A copy of the PM Sector Report is provided as an appendix to this paper.

### **Next steps**

- i. Members are asked to approve the PM Sector Report for publication.
- ii. The report will be edited by staff in the Communications Directorate and prepared for publication.
- iii. A copy of the report will be sent to members of the Histopathology Working Group for information prior to publication in June 2011.
- iv. Staff in the Communications Directorate will prepare a communications plan for the report, including publication on the HTA website and direct mailing to establishments during June 2011.

### **Final note**

7. We are particularly grateful for the contributions made by Professor Susan Dilly to shape the final structure and content of this report.



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (26/11)
<b>Agenda item</b>	10	<b>Author</b>	Allan Marriott Smith

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## Living organ donation consultation

### Purpose of paper

1. To seek the Authority's approval to proceed with the living organ donation consultation.

### Background

2. In November 2011 the Authority agreed that work was required to develop a framework for establishing which relationships in living organ donation cases should be classified as "known to" and "not known to".
3. The first steps of this work were undertaken in December 2010 by the Transplantation Working Group (TWG), with additional interested Authority Members in attendance. Members agreed to delegate oversight of further work to the Independent Assessment Working Group (IAWG).
4. In February 2011, the Chair sought and received agreement from Members that a public consultation should be held to help inform the Authority's decision.
5. The consultation document has been developed by the Executive with extremely helpful contributions from all members of the IAWG. The Executive intend to launch the 12-week consultation on Tuesday 31 May.

### Papers

6. The following papers are attached for the Authority's consideration:
  - Covering letter to consultation respondents
  - Consultation Document (the consultation questions start at page 11)

- Consultation Document Annex A - Independent Assessor Report
- Consultation Document Annex B - Examples of additional questions which could be asked of donors and recipient who have met online

### **Recommendation**

7. The Authority approves the launch of the consultation, subject to comments on the consultation document.

**Human Tissue Authority**  
151 Buckingham Palace Road  
London SW1W 9SZ

Insert recipient's name here  
Address

**Tel** 020 7269 1900  
**Email** [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)  
**Web** [www.hta.gov.uk](http://www.hta.gov.uk)

**Date** 31 May 2011

Dear

### **Consultation on relationships in living organ donation**

The Human Tissue Authority (HTA) is consulting on the relationships which may exist between a living organ donor and recipient, and how we go about regulating these donations.

As the way in which relationships are formed changes it is important that we are able to fulfil our regulatory role ensuring that living donors are consenting freely and have not been offered a reward.

We are asking 15 questions (which can be found on page 11 onwards) on how close a relationship needs to be for the donor and recipient to be considered known to each other, and whether or not there is a greater risk of a reward changing hands when the relationship is formed on line, or through a third party.

In the past, living donors and their recipients have normally been genetically related or have a well established relationship. Recently we have been asked how we would assess donations between people who have a more distant relationship, for example friends of friends who have never met, and also people who have formed a relationship via social networking websites.

We are committed to playing an active and facilitative role in living organ donation and would welcome your responses to support us in our policy making.

We would appreciate responses from any organisations or individuals who have an interest in this subject, and particularly those involved with living donation, those who have given or received an organ, and people that use social media sites to make friends.

The consultation closes on 23 August 2011 and we will be publishing a synopsis of responses in November 2011. The policy and assessment framework will be available in early 2012 and we will work with the transplant community to ensure this is successfully adopted.

Yours sincerely

Craig Muir  
**Chief Executive**

## **DRAFT – 16 May 2011**

### **The Human Tissue Authority**

1. The Human Tissue Authority (HTA) works to maintain confidence of the public and professionals by ensuring that human tissue is used safely and ethically, and with proper consent. We regulate organisations that remove, store and use tissue for research, medical treatment, post-mortem examination, teaching and display in public. We also give approval for organ and bone marrow donations from living people.
2. The HTA is committed to working with the public, those we regulate and others in shaping our policies and our operations.
3. The HTA is governed by a 12 Member Board composed of a mixture of professionals with direct knowledge of the regulated sector and lay people. They are supported by an Executive of 50 full time staff.

### **This document**

4. The beginning of the document sets out the background to the issue we are consulting on. The consultation questions start on page 11 of the document.

## **Definitions**

### **Independent Assessor (IA)**

An Independent Assessor is the person who conducts the interviews with the donor and recipient on behalf of the HTA and submits a report on the results of these interviews. IAs work in a hospital or related environment, and are considered by the HTA to be qualified to act in this capacity. IAs are trained by the HTA and go through an annual reaccreditation process.

### **Living Donor Coordinator (LDC)**

The Living Donor Coordinator is a nurse specialist responsible for coordinating living organ transplants in a transplant unit. They are responsible for the promotion, organisation and co-ordination of the Living Donor Transplant Programme, to lead and develop an effective and clinically excellent service.

### **Living Organ Donation**

Living Organ Donation is the donation of an organ or part organ from a living person to someone who requires a transplant. In the UK most living donations are of kidneys, although it is also possible to donate a liver lobe for transplantation.

### **Non-directed altruistic donation**

Non-directed altruistic donation is a form of living organ donation. It involves a donor coming forward who does not have an identified recipient, and wishes their organ to be transplanted to the person most in need on the national waiting list. The donor cannot attach any conditions to the donation, and may never know who received their organ. Non-directed altruistic donation was made legal by the Human Tissue Act 2004 (the Act). Since this form of donation became a practical possibility, there has been an increase in the number of people coming forward each year, with 40 people offering in 2010/11. All donations of this type have been kidney donations, although it is conceivable that a liver lobe could be donated altruistically.

Non-directed altruistic donation is defined as “the removal...of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him.”<sup>1</sup>

### **Organ**

An organ is defined as “a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy”.<sup>2</sup>

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<sup>1</sup> The Human Tissue Act 2004 (Persons who lack capacity to consent and transplants) Regulations SI 2006 no 1659 Regulation 12(5)

### **Paired and Pooled donation**

Paired donation is a form of living organ donation. It occurs when a person is fit and suitable to donate, but is incompatible with the potential recipient. A system exists whereby they are then matched with another donor and recipient in a similar situation and each donor donates to the other's recipient.

Pooled donation is a form of living organ donation. It follows the same principle as paired donation, but involves three or more donor and recipient pairs.

### **Part organ**

Material is part of an organ if it is to be used for the same purpose as the entire organ in the human body.

### **Transplantation**

An implant of an organ or part of an organ, tissue or cells either from and into the same body or from one person to another.

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<sup>2</sup> The Human Tissue Act 2004 (Persons who lack capacity to consent and transplants) Regulations SI 2006 no 1659 Regulation 2

## Introduction

### Regulation of Living Organ Donations by the HTA

1. This consultation document focuses on part of our role in regulating living organ donation.
2. Specific questions are posed throughout this document, and we would welcome your response to these, as well as any other comments you may wish to make.
3. All living organ donations carried out in the UK must be approved by the HTA before they can go ahead.<sup>3</sup> This is a requirement of the Act. If a living transplant did go ahead without this approval, the surgeon who removed the organ would be committing an offence.<sup>4</sup>
4. To give approval we must be satisfied that:<sup>5</sup>
  - The potential donor has not been given, or has been promised, a reward for the donation of their organ;
  - That the donor has freely given their consent for the removal of the organ; and
  - The removal of the organ is otherwise allowed under the law.
5. To allow us to do this we receive reports from Independent Assessors (IAs). We train and accredit over 130 IAs across the UK. IAs work in hospitals or related environments. They have no vested interest in the transplantation programme at the Transplant Centre or Unit they support. IAs interview donors and recipients, both separately and together, and submit a report of the interviews to the HTA. IAs come from a variety of backgrounds.
6. The report the IA submits to the HTA must cover:
  - Any evidence of duress or coercion affecting the donor's consent to donate;
  - Any evidence of an offer of a reward for their donation;
  - Any difficulties the IA has had in communicating with the person interviewed;
  - The understanding of the donor of the information given to them on the nature of the medical procedure and the risks associated with donation;

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<sup>3</sup> With the exception of organs removed from a patient for their own treatment which are subsequently transplanted, known as "domino donation" (paragraph 26, HTA Code of Practice on the Donation of solid organs for transplantation)

<sup>4</sup> s.33(1)(a) Human Tissue Act 2004

<sup>5</sup> The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

- The name and qualification of the person who gave this information to the donor;
  - The capacity of the donor to understand the medical procedure and associated risks, and
  - The understanding of the donor that they can withdraw their consent.
7. We use the IA's report in making our decisions. Who within the HTA assesses any particular case depends on the type of donation. In cases where the donation is between two people who are genetically related or who have an established relationship, trained members of HTA staff make the assessment. In more complex cases such as non-directed altruistic donation and paired and pooled donation or where the donor is a child or an adult who lacks capacity to give consent,<sup>6</sup> the assessment is made by a three member panel of the HTA Board. About 10% of the cases we receive each year are assessed by Board panels.
8. Once we have reached a decision this is communicated to the Living Donor Coordinator (LDC), IA and the clinician who referred the case to the HTA for assessment. The LDC passes this information on to the donor and recipient.
9. Most cases are approved by the HTA within a matter of days. There are occasions when we need more information to be satisfied that the requirements mentioned above are met, and we may ask an IA to undertake a follow up interview and submit a further report to us. In only a very small number of cases (two in 2010/11) we have concluded that we are not satisfied that the requirements have been met and have refused to approve the donation.
10. If we refuse to allow the donation to proceed, we notify those involved of the reasons why. The notification also explains that the donor and recipient may repeat the IA process or seek a reconsideration of our decision. There has been only one reconsideration hearing since we started regulating in September 2006.

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<sup>6</sup> If the donor is a child or an adult who lacks the capacity to consent court approval is required before the HTA can assess the case.

## Why we are Consulting

11. The HTA is responsible for assessing all living donations.<sup>7</sup> We have be clear about whether a planned donation is to someone know to the donor (a directed donation) or to a stranger (an altruistic donation). We are now exploring what relationships can exist where we can be sure about whether the donor and recipient are known to each other. This is important as it will help us safeguard public confidence in the manner in which we carry out our assessment of all living donor cases.
12. At present, as part of our approval process, we require all donors and recipients to prove their relationship to each other. For many this is very easy to do by producing their birth, marriage or adoption certificates. Sometimes the relationships are not certified so alternative verification must be produced such as utility bills in joint names, photographs spanning a number of years, or statements from a person in a position of authority.
13. The reason we ask for verification of the relationship is that it helps us build a picture of how and why the decision to donate was made, and in turn enables us to be satisfied that no reward is being offered or pressure placed on the donor to consent. Full guidance on how we seek to establish these relationships is set out the statutory Code of Practice *Donation of Solid Organs for Transplantation* September 2009.
14. Over the last 18 months the HTA has received enquiries from LDCs and potential recipients asking how we would assess a case where the donor and recipient had met via social media sites such as Facebook or Twitter. We have also received similar enquiries from donors and recipients who are not directly known to each other, but are friends of friends or have a connection through another relative, for example, the friend of a mother offering to donate to the son, who she or he has never met, because her relationship with the mother is strong and they want to help.
15. These enquiries have prompted us to seek legal advice on the issue of how we can further refine our understanding of how donors and recipients are known to each other. This is important as it will help us decide the level at which approval for such cases is made within the HTA. It does not mean that we would necessarily turn down a case for approval; the issue is the level of scrutiny that such cases are given within the HTA when they are ready for consideration. It should be noted, however, that in ALL cases, we do still have to be satisfied that there has been no reward given or promised, that there has been no duress and that consent is fully informed.

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<sup>7</sup> Prior to the Human Tissue Act 2004 living organ donation was governed by the Human Organ Transplants Act 1989. Under this legislation, if a genetic relationship could not be established through tissue typing the case was considered by the Unrelated Live Transplant Regulatory Authority (ULTRA).

16. If the donor and recipient are known to each other the case is assessed by a member of HTA staff, but if they are not known to each other the case is assessed by a panel of three Board Members. This is because it has been judged that donations between donors who are not known to their recipient may fall within the statutory definition of a non-directed altruistic donation, and need scrutiny on that basis by a panel of three Board members.
17. In the past, when we have received an enquiry where the relationship between the donor and recipient has been remote, we have provided advice on a case-by-case basis and assessment of the case has been made by a panel of Board Members. We have not yet been required to assess a donation between people who met online, but have assessed cases between a child recipient whose donor was a friend of their parents.
18. As an interim measure we now ask IAs to confirm in their report to us whether a donor and recipient are known, or not known, to each other. We are now consulting on the parameters that we can establish to give clearer guidance on the range of relationships where we decide that the donor and recipient are not known to each other.

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## The consultation issue – how the HTA should assess certain cases in future

19. This consultation focuses on *how* the HTA should assess these cases, not *whether* the HTA should assess these cases, as we need to ensure that we take the views of all interested parties into consideration when drafting an assessment framework. Specifically we need to define “known to” and “not known to”, and establish whether there is a way of satisfying ourselves that every possible type of case CAN meet the key criteria of no reward, no duress, and fully informed consent.
20. We would like your feedback on this issue which will help us develop the framework we will use to assess how we decide whether the donor and recipient are known to each other or not. For example, in cases where the donor and recipient have met, online and their relationship does not predate the recipient’s need for a transplant or where the relationship is remote, for example a friend of a friend, we will be able to decide whether this means that they are or are not known to each other.
21. The responses will also be used to help the HTA decide whether all such cases should be assessed by a panel of Board Members or whether there is a spectrum within the broad headings of meeting online and remote relationships with some cases requiring the extra scrutiny of Board panel consideration while others pose no increased risks and can be assessed by a trained member of HTA staff.
22. We may also seek to use this framework for assessing donations between genetic relatives who had never met each other prior to the need for transplantation arising, and who have no strong bond.
23. We have asked specific questions in each section of the consultation. If you would like to share any additional information with us, please do so in your response.
24. We welcome responses from all interested organisations or individuals, and would especially value the thoughts of people who may require a kidney or liver lobe transplant in the future, those that have been a living donor or recipient, Living Donor Coordinators, Transplant Surgeons and Independent Assessors. Any member of the general public is also welcomed to contribute to this consultation.
25. The consultation ends at 5pm on Tuesday 23 August 2011, and responses should be emailed to [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk) or sent to:

Vicky Marshment  
Head of Performance  
Human Tissue Authority  
151 Buckingham Palace Road  
London

SW1W 9SZ

26. We will collate the responses and publish a synopsis in November 2011.
27. We intend to publish the assessment framework in early 2012, and will work with the transplant community to support its smooth introduction.
28. If you have any questions about this consultation, or require it in a different format, please email [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk) or telephone Vicky Marshment on 020 7269 1960.

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**Known To and Not Known To**

29. The legal advice we received advised that while the legislation makes reference to not known to there is no further definition in the Regulations that give us assistance on where the boundary may lie. In general law, the advice we have received is that the terms “known to” or “not known to” had no special legal meaning, and that everyday English usage should apply.
30. Until relatively recently the way in which relationships were formed was limited. Two people would often meet physically, perhaps at school, at work, on holiday, or through mutual friends. Their relationship might be sustained through continuing to meet regularly, talking over the telephone, or by correspondence.
31. It has now, however, become increasingly easy to form relationships without physically meeting the other person. People may meet online through social media sites such as Facebook and Twitter, or they may meet in chat rooms designed to bring people together with a shared interest or concern.
32. Further, donors may come forward who are not directly linked to the recipient, but have a “once removed” relationship, for example a friend of a friend or a friend of a parent. These relationships can be difficult to prove.
33. When considering the type of remote relationships that may exist we identified the following scenarios, however these are not exhaustive:
  - a. **Friend of the family who the donor has not met**

A daughter goes home to visit her parents for the weekend. They mention that their friend, who they play darts with, is about to go on dialysis and their friends and family have been tested as potential kidney donors but none were suitable. The daughter says she wants to be considered as a donor as she knows that both the friend, and the darts team, are important to her parents.
  - b. **Friend of a friend who the donor has not met**

A man (Adam) in his 30's meets an old school friend once a month for a drink. At the most recent meeting his school friend tells him about a man he works with who has had to have time off recently as he has polycystic kidney disease and requires dialysis. As Adam is a blood and bone marrow donor he sees donating his kidney as a logical thing to do to help someone out, and he specifically wants to help his school friend's friend.
  - c. **A donor and recipient who have met online through a website specifically aimed at matching donors and recipients**

The Donor4you.co.uk website has recently been launched in England, and Stephen has registered as he has been on the waiting list for a kidney

transplant for 18 months and is becoming increasingly unwell. Stephen has no living relatives and two of his friends came forward to be tested as potential donors but were found not to be suitable. Dina goes on to the website after hearing about it on the radio and likes the look of Stephen. She notices they have the same taste in films and music. Dina decides she would like to donate to him, although she's never thought about anything like this before.

**d. A donor who has identified their recipient from a targeted television or newspaper campaign**

A daily newspaper has run the first of its monthly centre page spreads featuring the pictures and basic details of 20 people who need a kidney transplant. Mandip notices a 25 year old man who reminds him of his brother, who died last year in a car crash. Mandip feels that he opened this page of this newspaper, on this specific day, for a reason and that he's meant to help this man.

34. The HTA needs to establish whether a donor and recipient are known or not known to each other to determine who within the organisation should assess the proposed donation.

***Question One – Can two people who form a relationship over the internet be considered to be known to each other? Please give reasons for your answer.***

***Question Two – Can two people who have not physically met be considered to be known to each other? Please give reasons for your answer.***

***Question Three – Would you consider the donor and recipients in scenario's a-to-d to be known, or not known, to each other? Please give reasons for your answers.***

35. It is an offence to advertise an organ for sale, to advertise offering to purchase an organ or to advertise as a broker of organs who would financially benefit from the transaction. But it is not an offence to advertise as a donor who will not accept payment, or as someone in need of an organ who is not offering payment.
36. In some cases a relationship may be formed solely for the purpose of a living transplant taking place. For example, a person in need of a transplant may set up a Facebook Group asking for potential donors to come forward. The page might include information on the patient's blood group, why they need the transplant, and information on the donation process. If this page is public, anyone with access to Facebook could come forward as a possible donor.

***Question Four– Does it matter whether a donor and recipient only establish a relationship for the purpose of a living organ transplant? Please give reasons for your answer.***

***Question Five – Should a donor and recipient who only formed a relationship for the purpose of transplantation be classified as known to, or not known to, each other? Please give reasons for your answer.***

37. It has been suggested that there is a difference between a relationship and a connection because relationships involve an emotional bond whereas connections are simply links between people which have limited emotional depth.

***Question Six – Can the difference between a relationship and connection be explained? Is there any difference between the two? Please give reasons for your answer.***

***Question Seven – Would making a distinction between a relationship and a connection be a useful way of helping the HTA determine if a donor and recipient are known to each other?***

38. The HTA has to be satisfied that the donor is not being offered a reward, defined by the Act as being a financial or material benefit,<sup>8</sup> in exchange for their organ.
39. IAs ask both the donor and recipient separately whether a reward is being offered, and then interviews them together to assess how they interact with each other. There is an assumption that, when there is a long standing relationship, whether or not this is genetic, the donor's motivation is to see the recipient restored to health and that financial or material gain is unlikely to be a consideration.
40. In cases where the donor and recipient have met online it could be considered that there is an increased risk of a reward being offered because of the lack of an existing close emotional bond, and that in cases where the relationship was formed only for the purpose of donation the recipient is unlikely to have a personal interest in the recipient's improved health.
41. However, this position is based on the view that people only act to benefit themselves, and this position is not a given. The increase year on year of the number of people coming forward as altruistic donors could be seen as an indicator of a desire to help improve someone's health, with no knowledge of who that person is.

***Question Eight – Do you think there is an increased risk of reward when a donor and recipient have met online? Please give reasons for your answer?***

42. One possible way of reducing the risk might be to require all those wishing to donate or receive a donation of a living organ to sign a document confirming that: no money is or will change hands between them or with a third party; that neither the donor or anyone else stands to benefit materially because of the donation; and that they understand that if that turned out not to be the case a criminal offence would have been committed.

***Question Nine– Do you think that requiring donors and recipients to sign such a document will reduce the risk of reward? Please give reasons for your answer.***

***Question Ten – What else could the HTA do to reduce the risk of reward?***

## **Evidence of duress or coercion**

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<sup>8</sup> s.32(11) Human Tissue Act 2004

43. In order to approve a donation the HTA must be satisfied that the donor has freely consented to the transplant. This means that the donor has not been placed under any pressure to donate.
44. We have found in the past that duress and coercion are equally as likely to occur between people who are genetically related as those who are friends or partners.
45. Duress could mean a person being pressured into donating by a number of family members or told that they will be disowned if they don't do this. Coercion is likely to be an offer of some non-material benefit, for example, forgiveness for something that has happened in the past or being told how much more the recipient will love you.

***Question Eleven – Do you think there is an increased risk of duress or coercion in cases where the donor and recipient meet online? Please give your reasons for your answer.***

***Question Twelve – If you think there is such a risk, what steps could the HTA take to mitigate this?***

## Advertising

46. It is not an offence to advertise to be a donor or to advertise as a recipient seeking a donor, as long as no reward is requested or offered.
47. It is conceivable that media organisations may begin running articles and features on patients who need an organ in an attempt to assist them in finding a donor. Newspapers, magazines and television programmes may view this to be a human interest story which will appeal to their readers or viewers, and something which they can follow-up, effectively telling the story of the donation from beginning to end.
48. We are aware that the media will wish to act lawfully when running such stories, and to ensure that is the case the HTA is considering producing a good practice media guide that would provide a step-by-step guide to effective handling of such a media campaign and offer advice and support. We would make it clear in the guidance that failure to adhere to it could put the donation at risk.

***Question Thirteen – Should the HTA publish a good practice media guide? If so, what should this include? Possible options include: guidance on reward and what this means practically; guidance on what could be considered duress and coercion; information on the kind of media coverage which could cause problems with the HTA approving a donation; information on anonymity.***

## General points

49. Annex A contains a copy of the online form that IAs complete following their interviews with donors and recipients which shows the subjects they cover in those interviews.
50. Annex B contains the questions we suggest that IAs might ask where the donor and recipient have met online or have a remote relationship. These are designed to look into the donor's motivation. In cases of non-directed altruistic donation we have found that most people have very clear reasons for wishing to donate. Based on that, we believe that exploring the donor's motivation helps to form a picture that will enable us to be satisfied there is no reward being offered and that consent is being given freely.

***Question Fourteen – Do you think that the questions listed in Annex B are the right ones? Are there any additions, amendments or deletions that you would make to that list?***

51. Assumptions are often made about who uses the internet to form relationships and connections. Some think it is primarily a tool used by the young. There is evidence, however, that shows that older users and people from a range of socio-economic groups use social networking sites on a regular basis.<sup>9</sup>

***Question Fifteen – Would you look for an organ donor over the internet for yourself or for someone you knew? If yes, would you explore the option of family or friends donating first, and only turn to the internet if they were not a possibility?***

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<sup>9</sup> <http://www.statistics.gov.uk/cci/nugget.asp?id=8>

## **Independent Assessor Report**

### **Sections A to C**

I confirm that I read, understood and applied the guidance issued by the HTA.

<b>Case</b>	<b>IA Unique Identifier</b>
<b>Case Number</b>	<b>Date of Independent Assessment</b>

#### **Section A– Category of Transplant**

<b>Directed</b>	<b>Non-directed</b>
<b>Is the Transplant</b>	

**Type of organ or part organ to be transplanted**

#### **Section B– Details of donor, recipient and location of transplant**

<b>Last Name of Donor</b>	<b>Date of Birth of Donor</b>
<b>First Name of Donor</b>	

**NHS/CHI/hospital number/passport/driving license number**

<b>Last Name of Recipient</b>	<b>Date of Birth of Recipient</b>
<b>First Name of Recipient</b>	

**NHS/CHI/hospital number/passport/driving license number**

**Name of living donor co-ordinator – 1**

**Name of living donor co-ordinator – 2**

**Name of clinician responsible for donor**

**Name of Transplant Unit**

**Name of Transplant Centre**

**Is this a Private Case?**

**Section C– Evidence of relationship**

**Relationship of Donor to Recipient**

**Other Relationship**

**Relationship of Donor to Partner**

**Other Relationship**

**Please provide detail of the photographic and/or documentary evidence that you have seen that confirms the relationship of donor to recipient/partner in this case**

**Sections D to F**

**Section D- Is the donor a child or adult lacking capacity?**

**Child Donor**

**Adult Lacking Capacity Donor**

**Name of Person/s**

**Accompanying Donor**

**Relationship of Person/s**

**Other Relationship**

**Accompanying Donor**

**Date of Court Approval**

**Please provide further information on the court approval in the box below**

**Section E– Communication**

**Were there any difficulties in communicating with the donor?**

**What were the communication difficulties?**

**Language**

**Hearing**

**Speech**

**Other**

**If Other, Please  
specify**

**Please provide details of what measures were taken in this case to ensure the process was understood by the donor.**

**Language Used to Translate to**

**If a translator was used please provide details below**

**Name of Translator**

**Address of Translator**

**Telephone Number**

**I confirm that the translator was independent of the donor**

**Were there any difficulties in communicating with the recipient/partner?**

**What were the communication difficulties?**

<b>Language</b>	<b>Hearing</b>	<b>Speech</b>
<b>Other</b>	<b>If Other, Please specify</b>	

**Please provide details of what measures were taken in this case to ensure the process was understood by the recipient/partner**

**Language Used to Translate to**

**If a translator was used please provide details below**

**Name of Translator**

**Address of Translator**

**Telephone Number**

**I confirm that the translator was independent of the recipient/partner**

**Section F– Understanding of the risks and procedure**

**Please provide full details of the donor’s understanding and acceptance of the nature of the procedure and risks involved. Please provide specific information about what the donor understands the risks to be, and details of the wider implications and the effect upon their children and/or other dependent relatives**

**Name of Registered Medical Practitioner**

**Qualification of Registered Medical Practitioner**

**I can confirm that the registered medical practitioner named above has explained to the donor the nature of the medical procedure, the risks involved and any other wider implications**

**I can confirm that the donor understands the nature of the medical procedure**

**I can confirm that the donor understands the risks involved**

**I can confirm that the donor understands that they are able to withdraw consent at any time and understands the consequences of withdrawal for the recipient/partner**

**I can confirm that the donor and recipient/partner were seen separately and together-**

- **Not applicable as the recipient is a very young child**
- **Not applicable as the donor is a child or an adult lacking capacity**
- **Not applicable as the donor is an altruistic donor**

**Please provide further detail if necessary**

## **Section G to I**

### **Section G- Additional information for non –directed altruistic donation**

**Please provide full details that the meaning of altruistic donation has been made clear to the donor i.e. that under no circumstances will either the donor or recipient know of each other’s identity prior to donation and transplantation and that they may never know**

**Please confirm how you are satisfied that the donor has no evidence of current or past mental illness that affects their ability to donate altruistically with valid consent**

### **Section H-Additional information for paired/pooled donation**

**Please provide full details that the donor and recipient/ part, in order to determine (as far as possible) that there was no evidence of duress or coercion affecting the decision to consent in this case**

**Please provide full details of the discussion had with the donor and recipient/ partner, in order to determine (as far as possible) that there was no evidence of an offer or promise of a reward in this case**

**DRAFT – 16 May 2011**

**Annex B**

**Examples of additional questions which could be asked of donors and recipient who have met online**

**To be asked of both the donor and recipient**

1. How did you first come into contact with each other online?
2. How long have you known each other online?
3. How often do you chat online?
4. Did you come into contact with each other for the purpose of living organ donation?
5. When did you first (physically) meet each other?
6. Do you think you will keep in contact with the donor following the transplant?

**To be asked of the donor only**

7. Why do you want to donate a kidney/liver lobe?
8. Why do you want to donate to your recipient in particular?
9. When did you first consider living organ donation, was it before or after you came into contact with the potential recipient?
10. Do you have a history of altruism, for example do you donate blood or are you on the organ donor register?
11. What do you feel you stand to benefit from becoming a living donor?

**To be asked of the recipient only**

12. What prompted you to seek a donor online? (If appropriate)
13. Did you explore the possibility of other relatives or friends as your donor?
14. What do you feel the potential donor stands to gain from this process?



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (27/11)
<b>Agenda item</b>	11	<b>Author</b>	Alan Clamp

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## Regulatory Activity Report 1 January to 31 March 2011

### Purpose

1. This paper provides an executive summary of the latest quarterly Regulatory Activity Report (RAR). Following discussions at the Regulation Member's Group (RMG) meeting in March 2011, the format of the RAR has been changed to ensure that it provides an appropriate level of detail for Members. The full version of the RAR has been approved by the RMG and is supplied as the appendix to this short paper.

### Executive summary

2. The Regulatory Activity Report summarises the management of critical shortfalls, investigations, legal activity and serious incidents reported to the Human Tissue Authority (HTA).
3. No critical shortfalls against standards have been identified since the grading criteria were changed in November 2010.
4. Three investigations were undertaken in the final quarter of 2010/11 and there are no outstanding issues from these investigations.
5. Five legal notices were issued during the fourth quarter of 2010/11, four of which were special directions requiring action to be taken to ensure compliance with HTA standards. The fifth was a Notice of Proposal to Revoke a licence for an establishment that was deemed not to need a licence.
6. Sixteen Serious Untoward Incidents (SUIs) were reported in the last quarter of 2010/11, the same number as in the previous quarter. Nine of these are still

being investigated. All but three of the SUIs reported in previous quarters have now been investigated and closed.

7. Twenty-nine Serious Adverse Events and Reactions (SAEARs) were reported in the final quarter of 2010/11, compared with 25 in the previous quarter. Most of the SAEARs reported in the fourth quarter are still undergoing follow-up and assessment. HTA staff are continuing to work with the Patient Treatment (Human Application) sector to raise the profile of reporting SAEARs in a timely manner, but this remains an area for improvement.

### **Action**

8. Members are asked to note the contents of this report.

## Appendix: Regulatory Activity Report

1. This paper provides a high-level summary to the Authority of how the HTA manages information relating to actual or potential breaches of the regulatory framework (“breaches”), both internally and externally. This report provides information on:
  - a. **critical shortfalls:** any critical shortfalls identified against licensing standards;
  - b. **investigations:** how the HTA deals with information it receives about breaches, including investigation of allegations from external sources, regulatory action panels convened, and management of information obtained through routine and non-routine inspections;
  - c. **legal activity:** legal activity associated with the management of breaches, including issuing legal notices and responding to requests to hear representations/appeals; and
  - d. **incidents:** serious incidents routinely reported to the HTA from licensed establishments in the post mortem and human application sectors.

### Critical shortfalls

2. The HTA began grading shortfalls against licensing standards as minor, major or critical on 1 November 2010. The assessment of each shortfall is carried out by the Regulation Manager following a site visit inspection, using a pre-defined set of criteria provided with each inspection report. Critical shortfalls are those of such significance that the HTA would normally expect activities to cease immediately until the shortfall could be addressed, whereas major and minor shortfalls usually require the Designated Individual to advise the HTA of how and when they will address the shortfalls.
3. To date, no critical shortfalls against standards have been identified.

## Investigations

4. Three investigations within the human application sector were carried out during the quarter:
  - a. Two investigations were conducted following allegations made/information obtained of licensable activities being carried out by an unlicensed establishment:
    - i. in the first case, the HTA became aware of the unlicensed supply of tissues/cells through its routine collection of data on third party suppliers to licensed establishments. The HTA investigated and found that the establishment was importing tissues and cells for human application without the required licence. The establishment was instructed, and agreed, to cease licensable activities until such time as a licence had been granted.
    - ii. The second allegation was made to the HTA enquiries line by a professional working within the regulatory framework. They believed that a competitor company was importing tissues and cells for human application outside of the licensing framework. The HTA investigated and found that the unlicensed company was intending to conduct licensable activities in the future, however they had not yet commenced any such activities and did not intend to do so until the HTA had granted a licence.
  - b. The third investigation followed an allegation made by a member of the public who was concerned that an HTA licensed establishment had transported tissues and cells for human application in a manner that may have compromised the safety and quality of the tissues and cells. The procurement and distribution took place in another European Member State. The HTA investigated and concluded that the matter did not give rise to a Serious Adverse Event for the HTA-licensed establishment that was to store the tissues or cells and provided the person making the allegation with the contact details for the other relevant Member State for further investigation.

5. A sector-specific breakdown of investigations carried out during the last year is below:

	HA	PM	PD	R	A
10/11 Q4	3	0	0	0	0
10/11 Q3	2	0	0	0	0
10/11 Q2	0	0	0	0	1
10/11 Q1	5	0	0	0	1

6. The increase in investigations for the human application sector could be linked to factors such as:
- The large size of the sector (272 licensed establishments), particularly compared to the PD (18) and A (47) sectors
  - potentially increased awareness in the sector of reporting incidents due to the reporting systems already in place (e.g. SAEARs);
  - the HTA collects more data on this sector than others (e.g. annual activity data);
  - this sector involves commercial establishments which may have an interest in making allegations about competitors; and/or
  - due to the inherent risk in the sector, people may be more willing to report or otherwise seek advice from the HTA about incidents that occur.

### **Regulatory Action Panels (RAP)**

7. One RAP was convened during the quarter following a routine site visit inspection of a human application establishment. A number of shortfalls against standards for consent and testing were identified during the site visit inspection, causing the lead inspector to refocus the inspection and convene a RAP to support the process for determining what risk-based, proportionate action to take.

Following the RAP, special directions were issued to the establishment directing the Designated Individual (DI) to address the shortfalls against the consent standards in a short period of time (one month). Additionally, the RAP determined that a full follow up site visit inspection will be undertaken to follow up on elements not able to be assessed due to the re-focussing of the first inspection, as well as check improvement in accordance with the establishment's Corrective and Preventative Action Plan. The DI has now submitted some evidence of compliance with the consent standards which is in the process of being assessed.

8. A sector-specific breakdown of RAPs convened during the last year is below:

	HA	PM	PD	R	A
10/11 Q4	1	0	0	0	0
10/11 Q3	0	0	0	0	0
10/11 Q2	0	0	0	0	0
10/11 Q1	3	0	0	1	0

9. As RAPs are designed to deal with complex issues, they are often convened as part of an investigation. It is perhaps unsurprising that there are higher numbers of RAPs in the HA sector, where the majority of investigations are also carried out. The factors outlined in paragraph 6 above could therefore also apply to why the numbers of RAPs are higher in the HA sector.

### Non-routine inspections

10. One non-routine (announced) inspection of an HA establishment was undertaken during the quarter. Following a routine inspection of the establishment in Q4 2009/10 when a range of shortfalls against standards were identified, the lead inspector decided to allow the establishment the opportunity to improve standards and assess its performance again at a follow-up site visit inspection. The non-routine inspection demonstrated that standards had improved to an acceptable level.

11. A sector-specific breakdown of non-routine inspections carried out during the last year is below:

	HA	PM	PD	R	A
10/11 Q4	1	0	0	0	0
10/11 Q3	2	2	0	0	0
10/11 Q2	0	0	0	0	0
10/11 Q1	1	2	0	0	0

### Legal notices

12. Five legal notices were issued during the quarter:

- a. special directions were issued to an HA establishment following a site visit inspection and subsequent Regulatory Action Panel (see paragraph 7 above);
- b. special directions were issued to an HA establishment following a site visit inspection which raised concerns about the suitability of the DI and the governance of the licence. The directions were to restrict the activities at the establishment to those which the lead inspector was satisfied could be appropriately managed while the DI was changed. Subsequently, the DI has been changed and the lead inspector intends to assess compliance further during a follow up site visit inspection once the establishment has improved their practices;
- c. two sets of special directions were issued to DIs in the post mortem sector to take responsibility for storing records made during human application activities. The HTA requires raw data and traceability records made during human application activities to be stored on HTA licensed premises if the HA licence is revoked; this is intended to ensure that the HTA can access relevant records following a serious adverse event or reaction even where the HA licence does not exist. DIs in the post mortem sector for the hospitals where the HA activity was ceasing agreed to take responsibility for the records and facilitate the HTA's access to those records;
- d. special directions were issued to an establishment in the HA sector revoking previous directions issued in Q3. The Q3 directions had restricted activity until improvements against standards could be demonstrated, the Q4 directions enabled the establishment to recommence activities under the licence;
- e. one Notice of Proposal to Revoke a post mortem sector licence was issued following a site visit inspection which concluded that no licensable activities were being carried out. The establishment applied for a post mortem sector licence to store relevant material for use for a scheduled purpose in 2008. The establishment receives samples of relevant material for specialist analysis, for which there is a licensing exemption in place. The HTA's original decision to grant a licence did not take this exemption into account and was therefore in error.

During a routine inspection of the establishment, the lead inspector identified that all storage of relevant material at the establishment was, and always had been, covered by exemption. Following this determination, in order to put things right, the HTA is intending to fully refund the licence fees paid by this establishment.

The HTA is satisfied that this incident is isolated in nature and an audit of current licensed establishments has since been carried out to demonstrate that this situation is unique.

13. A sector-specific breakdown of legal notices issued during the last year is below:

	HA	PM	PD	R	A
10/11 Q4	2	3	0	0	0
10/11 Q3	2	0	0	0	0
10/11 Q2	4	0	0	0	0
10/11 Q1	4	0	0	0	0

### Representations or appeals

14. The HTA did not receive any notification of intention to make representations or appeals during the quarter.

15. A sector-specific breakdown of representations or appeals heard during the last year is below:

	HA	PM	PD	R	A
10/11 Q4	0	0	0	0	0
10/11 Q3	0	0	0	0	0
10/11 Q2	1	0	0	0	0
10/11 Q1	0	0	0	0	0

16. The Representations heard in Q2 related to a number of conditions proposed to be added to a licence following a routine site visit inspection. The detail of this Representations Hearing was provided to the Authority in a previous Regulatory Activity Report (November 2010). The matter was resolved in October 2010 and no further action has gone on as a result.

**Serious untoward incidents (SUIs) reported in the post mortem sector***SUIs reported this quarter*

17. 16 SUIs were reported this quarter, the same number as reported in Q3. This is a relatively small number of SUIs given that the HTA estimates that, on average, around 30,000 post mortem examinations are carried out per quarter.

# of SUIs	SUI category	Status	Compare Q3
1	Accidental damage to a body before or after PME	1 closed	-1
4	Any incident that may result in adverse publicity that may lead to damage in public confidence	1 closed 3 ongoing	-3
2	Discovery of an organ or tissue following post mortem examination and release of body	2 closed	-1
1	Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	1 ongoing	+1
2	Major equipment failure	2 closed	+2
2	Post-mortem examination (PME) conducted was not in line with the consent given or the PME proceeded without adequate consent	2 ongoing	0
2	Release of the wrong body	1 ongoing 1 closed	0
2	Serious security breach	2 ongoing	+2

Table 1: Numbers of serious untoward incidents in the PM sector reported to the HTA this quarter

18. The Histopathology Working Group decided in January 2011 that five days should be the maximum length of time to report an SUI from discovery, although establishments are strongly encouraged to report these to the HTA as soon as practicable. This requirement was communicated to the sector through the April e-newsletter to take effect from 6 April 2011. Future Regulatory Activity Reports will provide detail to the Authority on the time taken to report SUIs to the HTA and any trends that occur.

19. The investigation of an SUI is carried out by the establishment where the incident occurs. A member of the HTA's SUI team assesses and grades each reported SUI for severity, and works with the establishment to provide support

and advice to ultimately ensure that appropriate actions are carried out and in a timely manner.

20. For clarity, the initial SUI report alerts the HTA to the incident but the establishment is not expected to be able to submit a full investigation or follow up report immediately. The Regulation Manager dealing with the SUI agrees with the DI a deadline by which the report should be provided, to allow reasonable time for the establishment to carry out a root cause analysis and advise the HTA of any corrective or preventative actions being taken as a result. An SUI is only considered closed when the HTA is satisfied that the incident has been investigated and appropriate actions taken. For this reason, many SUIs will be reported and closed in different quarters, reflected by the “ongoing” or “closed” status described in the above table. Where SUIs are ongoing longer than the expected 2 month period, these are reported below.

*Update on ongoing SUIs from previous quarters*

21. One SUI reported in Q2 remains ongoing. The establishment voluntarily ceased activities following a CPA inspection which found them unsuitable to maintain accreditation. The establishment has chosen not to revoke their HTA licence until such time as they can determine whether to resume activities in the future (which is dependent on funding). The HTA has since undertaken a routine inspection of this establishment and found all applicable standards to be either “almost met” or “fully met”.
22. Two other SUIs reported in Q3 remain ongoing and will be reported on in future reports.

**Serious adverse events and reactions (SAEARs) reported in the human application sector**

*SAEARs reported this quarter*

23. 29 SAEARs were reported this quarter, compared to 25 in Q3. Most of these reports are still undergoing follow-up and assessments, mainly due to the fact that the time allowed for investigation and follow up often spans more than one quarter (as in paragraph 20 above).

*24 hour requirement for SAEARs reporting*

24. In October 2010, the HTA communicated a mandatory requirement to the sector to report SAEARs within 24 hours of discovery of the SAEAR. The requirement came into force with the issue of General Directions for the HA sector (Directions 003/2010) on 12 November 2010, implementing the ‘Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment’. The new requirement had also been communicated to

attendees at the October 2010 HA sector conference and through the October 2010 e-newsletter (which continues to be available on the website).

25. The reasons given for the updated timescales were given as: “The HTA considers it essential that the current time gap between the discovery of an SAE / SAR and reporting is substantially shortened to enable us to fulfil our duties of alerting all relevant establishments, bodies and authorities in cases where they raise health concerns that have wider public health implications and which reach beyond the establishment immediately affected”.
26. HTA staff are continuing working to proactively raise the profile of SAEARs reporting in this sector to encourage reporting but acknowledges that this has not yet been fully realised as it will take some time for a culture of reporting to bed down in the sector.

#### *Time taken to report SAEARs*

27. The HTA is aware that there is some concern within the Authority about the time being taken to report SAEARs, particularly given that this mandatory requirement is now in effect. Whilst the HTA acknowledges that progress towards achieving the target of 24 hour reporting is slow, it may be beneficial to provide some explanation of contributing factors.
28. In previous regulatory activity reports to the Authority, the HTA has reported on the number of days between the SAEAR *occurring* and the date of reporting – not the date of *discovery* to the date of reporting. This, along with other factors (discussed below) may appear to inflate the length of time that it takes for SAEARs to be reported. The HTA are currently updating the systems for capturing this information to ensure that the most useful information can be reported on. A new field for capturing “date of discovery” has been added to the SAEARs reporting form, however this field was added at the end of Q4 and so full data for Q4 SAEARs reports is not available. The Authority are asked to note that times reported below are therefore on the basis of time from occurrence to reporting.
29. Out of the 29 SAEARs reported in Q4, 7 were reported within 24 hours of occurrence. The majority were reported within approximately 2 weeks of occurrence, and 9 were reported in excess of 40 days after the SAEAR had occurred (with 6 being reported in excess of 100 days). Prior to the gathering of new data on the ‘date of discovery’, HTA had already asked for feedback from staff in relation to timing of submissions. Reasons given mainly related to delayed reporting to the tissue establishments by the clinician and end users, or the bleated realisation that an event was reportable, with this only being brought to their attention, for example, during an inspection.

30. The HTA is aware that many SAEARs reported late (i.e. 40+ days) are reported to the HTA following advice given on site-visit inspection. Often, establishments may not be fully clear on what constitutes an SAEAR and so have not proactively reported these. In these situations, the inspection team reviews the establishment's incident reporting procedures to determine whether they are insufficient or not being followed. Where improvements to the internal processes are required, this would be identified as a shortfall in the inspection report and the DI would be expected to take action to rectify the situation. The lead inspector may also review the establishment's risk profile, which could cause a re-inspection to be scheduled sooner.
31. Whilst on inspection and when dealing with enquiries, Regulation Managers consistently emphasise the importance of reporting all possible or suspected SAEARs for the HTA's assessment but it will take a significant period of time before all HA establishments are inspected with this relatively new requirement in place.

*Regulatory action as the result of a SAEAR*

32. The HTA is further aware that there is some concern within the Authority about whether appropriate regulatory action is taken as the result of late reporting of SAEARs. In order to fully address these concerns, there is a distinction to be made between regulatory action taken as the result of a SAEAR indicating a breach of standards and action taken as the result of late reporting:
- a. **action taken as the result of a breach:** every SAEAR reported to the HTA is assessed by a member of the SAEARs team. Where the report indicates that a failure to meet standards has contributed to the event or reaction occurring, an investigation may be carried out and/or proportionate regulatory action is taken where appropriate;
  - b. **action taken as the result of late reporting:** the HTA has made a strategic decision not to penalise establishments for late reporting of SAEARs as this would potentially dis-incentivise future reporting.
33. To ensure that this approach is fit for purpose into the future, the SAEARs team are now collecting data on "time of discovery" so that establishments can be queried on why it has taken them so long to report, which may influence our future strategic direction when dealing with SAEARs reported to us.
34. The HTA continues to seek feedback from establishments about reasons for delayed reporting, and proactively gives advice about required reporting timelines:

- a. the SAEARs webpages are currently being reviewed, with more emphasis to be placed on the requirement to report within 24 hours and on how to correctly fill out the online form;
  - b. a benchmarking exercise will be undertaken to compare the experience of the HFEA and MHRA, who have similar reporting requirements; and
  - c. information will be gathered about adherence to the timelines and follow-up where timelines are not adhered to, to inform future steps.
35. Finally, to help create a reporting culture, the 2011/12 business plan includes an objective to host stakeholder workshops to roll out tools for identifying, grading and reporting SAEARs.

*Update on ongoing SAEARs from previous quarters*

36. 3 SAEARs from Q3 are ongoing and will be reported on in future reports.

**Conclusion**

37. Members are asked to note the contents of this report.



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (28/11)
<b>Agenda item</b>	12	<b>Author</b>	Adam Whittaker Alan Clamp

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## Summary of post-inspection feedback for 2010/11

### Purpose

1. The aim of this paper is to provide the Authority with a summary of the post-inspection feedback for the 2010/2011 business year.

### Background

2. The Regulation Directorate provides all individuals who have been involved in an HTA site-visit inspection of their licensed establishment with the opportunity to provide feedback on their experience.
3. The Authority received a paper at the January 2010 meeting giving details of the first three-quarters of the business year's data. This paper provides the post-inspection feedback data for the entire 2010/2011 business year.
4. In March 2011 a new question was added to the post-inspection feedback questionnaire. Question 7 asks establishments 'Has the inspection process helped improve the way you work?' and aims to provide another indicator of how effective and useful licensed establishments find the inspection process. An analysis of the responses to this question will be included in subsequent reports.
5. A new practice of emailing an electronic copy of the establishment post-inspection feedback form to the DI during the day following the inspection has now been introduced. The aim is to increase the ease of providing feedback by removing the need to copy paper forms and return them to the Human Tissue Authority (HTA) via the post.

6. Information gathered from establishments continues to be:
- directly fed back to the lead and support inspectors for personal development
  - sent to the line manager (a Head of Regulation) to feed into the Performance Development Plan (PDP) process
  - shared with the Regulation Directorate at regular intervals
  - reported to the Authority as an indicator of performance
  - used to identify areas where HTA's inspection processes or procedures could be improved
  - used to inform training for Regulation staff.

### **Summary of feedback**

7. One hundred and ninety four inspections were carried out during the 2010/2011 business year. The breakdown according to sector is set out below:
- Human Application = 89
  - Post Mortem = 76
  - Research = 21
  - Anatomy = 4
  - Public Display = 4

58% of licensed establishments provided feedback.

8. Overall during the 2010/2011 business year, the respondents from establishments demonstrated a very high level of satisfaction with HTA inspectors and the HTA inspection process. 100% of respondents answered question six ('Please rate the overall inspection process') as either good or excellent. Of these, 34% rated it as good and 66% rated it as excellent. The proportion of excellent ratings varied as follows:
- Human Application (124 respondents) = 66% excellent
  - Post Mortem (140 respondents) = 71% excellent
  - Research (45 respondents) = 47% excellent
  - Anatomy (5 respondents) = 100% excellent
  - Public Display (1 respondent) = 100% excellent
9. There were no significant differences in responses over time (measured by comparing the responses in each quarter). A very small number of forms (less than 10) were returned anonymously and were not allocated to establishments or sectors. The overall ratings on these forms were not significantly different from the rest of the forms.

## **Next Steps**

10. To monitor on a quarterly basis the response rates, overall satisfaction ratings and the response to the new question about whether the inspection process has helped to improve the way establishments work. This information will be reported to the Authority.
  
11. The Regulation Directorate will continue to use the feedback to review processes and, where appropriate, actions will be taken to improve the effectiveness and usefulness of the inspection process.

## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (29/11)
<b>Agenda item</b>	13	<b>Author</b>	Vicky Marshment

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## Absence of a presumed genetic link – update

### Purpose of paper

1. To give an update on this issue one year after the Authority considered this matter, and to propose an amended position

### Background

2. The issue of the discovery, during work-up, of the absence of a presumed genetic relationship between a donor and recipient pair was discussed at the September 2009 (HTA (31/09)) and May 2010 (HTA (19/10)) Authority Meetings.
3. The Authority's decision was that the issue did go to consent and a policy position was agreed. A letter to Transplant Units (Annex A) and a model form for capturing the donor's decision were agreed. The letter sets out the Human Tissue Authority's (HTA) guidance that the donor's wishes are addressed so that in the event that a presumed genetic relationship is found not to exist, the donor's wishes on disclosure have already been established.
4. It is 11 months since the policy position agreed at the May 2010 Authority Meeting was implemented. This paper draws on the valuable experience we have gained in this area and also reflects the legal advice we have received.

### Current position

5. An inadvertent by-product of the testing required to assess whether a potential living donor is suitable for their recipient is the possible confirmation of the existence of, or discovery of the absence of, a presumed genetic relationship. This could occur in donations between fathers and their children, or siblings. In

one case the discovery was made when the mother told the surgeon that the father was not the genetic father.

6. The HTA position, detailed in the letter sent out to all Transplant Units in June 2010, was that this issue is raised with the potential donor, preferably at the very beginning of the work-up process so they may state whether or not they wish to be informed if the presumed genetic relationship is discovered not to exist.
7. The HTA takes the position that this matter is addressed by Transplant Units in a way they decide is appropriate, and which takes into account the HTA suggestion that this matter is considered at the start of the work-up process. This position has been broadly accepted by the those working in living organ donation and for the main part, works well (this information was gained through informal discussions, rather than a formal review of the process).
8. The HTA letter sets out the position that the matter must have been addressed with the donor before the case comes to the HTA for approval. This could be read as a policy position that the HTA would not even consider a case for approval unless this discussion had taken place and the donor's wishes were known.
9. The Head of Legal has advised that placing a restriction that would prevent the HTA from even considering the case for approval is a position that goes beyond the HTA's statutory remit because there is no legislative provision that allows the HTA to refuse to consider a case for approval. In cases where the donor has not been asked whether they would want to be informed of misattributed paternity, the HTA cannot state that the donor must be given this information before the case is considered. Such a statement takes us beyond our remit. The HTA should make any decision based upon the facts presented in the Independent Assessor's (IA) report, rather than refuse to consider the case. (Annex A highlights the paragraphs in which we make statements which are beyond our remit).
10. In our limited experience we have known cases where when paternity was disproved the donor withdrew their consent, and cases where the donation went ahead. There is not a standard response of donors when they are told that they do not have the genetic relationship with the recipient that they thought they had.
11. Research in this area has found that transplant physicians do not hold a unified view on whether or not a donor should be informed.<sup>1</sup> This highlights the close

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<sup>1</sup> [Transplantation](http://www.ncbi.nlm.nih.gov/pubmed/19461476). 2009 May 27;87(10):1429-35 (<http://www.ncbi.nlm.nih.gov/pubmed/19461476>)

relationship between the law of consent and the law of confidentiality in this area.

### **Next steps**

12. We will write to all Transplant Units reaffirming the recommended approach of addressing this matter prior to work-up commencing while recognising that the policy position allows each Unit to take its own approach. Because the policy has been in place for nearly a year, it is highly unlikely that a Unit is not aware of a current donor's wishes, although we would want to check that there are no long term cases still ongoing where the work up started before June 2010. If that is the case, we would suggest that the Unit write to us to confirm that they are dealing with this issue with those donors.
13. This letter will make it clear that a failure to ascertain the wishes of the donor will not automatically lead to the case been rejected by the HTA.
14. The letter will be shared with Transplant Working Group (TWG) Members for sign off.

### **Legal Review**

15. This paper was reviewed on 12 May 2011.

### **Action**

16. The Authority should note the proposed next steps.

**Human Tissue Authority**

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**Date** 21 June 2010

Dear

**Absence of a presumed genetic relationship**

The increase in the number of living organ donations over recent years has brought to our attention a very rare situation which goes to the issue of fully informed consent. Very occasionally a situation arises when a presumed genetic relationship between a donor and recipient may be found not to exist. There have only been a handful of cases where this has been discovered during compatibility testing, however we are mindful that a consistent and fair approach should be established.

We would like to thank you for responding to the questions we sent out, which helped to inform this policy. Following your comments, the policy was discussed by the Authority in May 2010.

**HTA recommendation**

When a case comes to the HTA for approval, if it has been established that a presumed genetic relationship does not exist, **we require the issue to have been addressed with the donor.**

It is up to the individual transplant units to decide how to deal with this and we know that the expertise, knowledge and skills of the transplant team will be essential to this process. We do suggest however that the following steps are taken.

1. The living donor coordinator (or another suitable member of the transplant team) explains to the donor at the beginning of the process that the testing which will take place may or may not confirm the presumed genetic link between them and the recipient.
2. The donor is asked whether or not they wish to be informed, if it is found that the presumed genetic relationship does not exist.
3. A signed record of the donor's decision should be kept on their file.

If it comes to light during work-up that the presumed genetic relationship does not exist, the unit will have clear instructions whether or not to inform the donor. If the donor has stated they wish to be told, and once told decide they still wish to proceed with the donation, then this should be made clear in the letter referring the case to the Independent Assessor.

HTA (29/11) Annex A

**Next steps**

This requirement is effective immediately. Any case we receive, in which the presumed genetic relationship has been found not to exist, will only be considered for approval if it is clear the matter has been addressed with the donor and the donor's wishes followed.

We have enclosed an example of a disclaimer form which you may find useful.

If you have any questions about this approach please either email [transplants@hta.gov.uk](mailto:transplants@hta.gov.uk) or call the Transplant Team on 020 7211 3400.

Yours sincerely,



**Vicki Chapman**  
Director of Policy and Compliance

Enc: example disclaimer form

## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (30/11)
<b>Agenda item</b>	14	<b>Author</b>	Ariel Armarego-Marriott

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## Human Tissue Authority public meeting and Annual Review event update

### Purpose of paper

1. To provide an update on the organisation of the next Human Tissue Authority meeting scheduled for 26 July 2011. This year, in an effort to be more efficient and provide value for money, we are combining this public meeting with our Annual Review of the year.

### Venue

2. The Wellcome Trust Conference Centre has been booked for the meeting. A light lunch and afternoon tea will be provided on the day, giving Authority Members and guests the opportunity to network.

### Agenda

- 10:00 – 10:30: Registration for Public Authority Meeting
- 10:30 -- 13:00: Public Authority Meeting followed by Q&A session from the audience.
- 13:00 – 14:00: Lunch
- 13:30 – 14:00: Registration for Annual Review
- 14:00 – 16:00: Annual Review event

### Public Authority meeting

3. This is a normal Authority meeting held in public, followed by a Q&A session.

## **Annual Review event**

4. This year's Annual Review will have fewer presentations. The event will start with an introduction from Diana Warwick. Craig Muir will then provide an overview of the year; and Alan Clamp will talk about the Human Tissue Authority's (HTA) approach to regulation.
5. This will be followed by an update and Q&A session on the Arm's Length Bodies Review.
6. The second half of the afternoon will be a debate, part of the consultation on organ donation arranged through social networking (see paper HTA (26/11)). The format will be the same as in previous years. Speakers will present for 5 minutes each on the various perspectives and the audience will be asked to vote on a series of propositions. The audience will be given the opportunity to ask questions and discuss their own position.



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (31/11)
<b>Agenda item</b>	15	<b>Author</b>	Allan Marriott Smith

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## Strategic Performance Review – April 2011

### Purpose of paper

1. To inform Members of progress against key performance indicators (KPIs) during January. Members are asked to note the contents of the report.

### Background

2. The Authority has agreed to monitor a set of KPIs that demonstrate whether the Human Tissue Authority's (HTA) strategic aims are being delivered. This is the first month of reporting against the KPIs agreed for the business year 2011/12.

### Progress in April 2011

### Regulation

3. KPI (1.7 and 1.13) of **at least 90% of Corrective and Preventative Action (CAPA) plans are completed within agreed timescales** was red for Patient Treatment (Human Application) sector establishments (KPI 1.7) and for establishments regulated under the Act (KPI 1.13). 22 out of 31 CAPAs remained open beyond their April deadline. Although it is the responsibility of establishments to complete their CAPAs, the HTA wishes to promote timely compliance and will need to reinforce this with establishments, following up those whose CAPAs are due to be completed in April or May 2011. This will be taken forward by Regulation Managers and monitored within the Regulation Directorate.

4. KPI (1.9) of ***the RAG status of the ODD project remains Green or Amber during the project implementation stage*** was amber due to the tight implementation timescales for the ODD project (see paper HTA (23/11)).

### **Strategy and Quality**

5. All KPIs were on track at the end of April.

### **Communications and Public Affairs**

6. All KPIs were on track at the end of April.

### **Resources**

7. All KPIs were on track at the end of April.

### **CEO**

8. The ***vacancy rate*** (KPI 3.1) was judged amber with an outturn of 8% against a target rate of 5%. This rate has been calculated by taking the complement of staff required to deliver the business plan that has been agreed by SMT as of the end of April (50) and the number of vacancies which are still in the process of being recruited (four). The outturn is amber as there currently active plans in place to recruit to these vacant posts.
9. The ***attrition rate*** (KPI 3.2) was judged amber. The rolling annual attrition rate year to end of April 2011 was 36%. One member of staff left the organisation in April having resigned to take up a post in another organisation.



## Authority paper

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<b>Date</b>	24 May 2011	<b>Paper reference</b>	HTA (32/11)
<b>Agenda item</b>	16	<b>Author</b>	Sue Martin

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## Financial report - May 2011

### Introduction

1. This paper provides an update of the Human Tissue Authority's (HTA) financial position as at 31 March 2011, following the audit, and highlights of the position at the end of April.
2. The report provides commentary on the following areas:
  - budgets
  - update of financial position to 31 March 2011
  - position to 30 April 2011
  - financial risks

### Budgets

3. The Department of Health (DH) are considering the HTA's case for additional revenue Grant-in-aid (GIA) for 2011/12 for the implementation of the Organ Donation Directive. We have requested £139.5k (or £113.5k if DH fund some costs directly) and expect to hear the outcome soon. In addition, the HTA expects that around £75k of capital funding will be required. DH has not yet allocated capital funding.
4. DH have indicated that the efficiency controls that have been in place for the last year are being reviewed to better take account of Arms Length Bodies' (ALB) circumstances while providing assurance that spend is necessary. The outcome is to be communicated at the end of May.

### Update of financial position at 31 March 2011

5. The annual accounts report expenditure of £5,337k for the year. Income from activities (licence fees and other income) was £4,247k and GIA was £1,059k. Income from activities is reduced by the unused licence fees collected in 2010/11 (£854k), that are being credited to establishments against 2011/12 fees. The rebate of unused licence fees from earlier years of £1,138k is shown as an exceptional item.
6. The statement of net expenditure shows net expenditure of £1,091k (before exceptional items). GIA is recorded as financing, and that reduces the deficit to £32k.
7. DH funded the refurbishment of 151 Buckingham Palace Road and has transferred the asset (£1,014k) to our balance sheet (the report titled Statement of Financial Position). This increases the non-current assets we hold.
8. The National Audit Office (NAO) completed their audit on 13 May and there were no issues of concern. They were pleased to see that the presentation of the accounts had improved since last year and have made only minor suggestions about the disclosures we make.
9. The Audit Committee will review the accounts and the report from NAO (the ISA 260 Report) at their meeting on 2 June. The annual report will also be presented to the Audit Committee. The Committee inform the signing of the annual report and accounts by the Chief Executive, before certification by the Comptroller and Auditor General. The report and accounts are then laid before Parliament and published. We expect publication at the end of June.

### **Financial position to 30 April 2011**

10. The position after one month of the financial year has been reviewed at a high level. More detailed review will take place next month.
11. Invoices were issued to human application establishments in April and have generated £44k more income than expected.
12. Expenditure on staff costs is around £20k less than budgeted, due to vacancies.

### **Financial risks**

13. Financial risks continue to be considered on an ongoing basis. Below is a table of the risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high level strategic risks that SMT have identified and are managing.

Risk	Link to the HTA's strategic risks	Mitigating actions and controls
A significant under-spend leading to a loss of stakeholder confidence in HTA's ability to manage resources effectively.	Inadequate relationship management	Identification of the likely outturn as early as possible. Credit of unused licence fees to establishments.
Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income.	Insufficient financial resources  Failure to manage change	HTA undertake a periodic review of establishments and expected income. Budgets would then need to be managed to reflect income or unavoidable costs recovered through licence fees.
Lack of prompt payment by licence fee payers affects cash flow and operations generally adversely.	Insufficient financial resources	Revenue collection will be closely monitored and the HTA's credit control and debt collection procedures used to pursue and recover all late payments.
The HTA is required to undertake additional functions or activities not planned or costed within the approved budget.	Insufficient financial resources  Failure to manage change  Inability to carry out its statutory remit	The HTA's financial management and governance arrangements will be used to identify any opportunities that may arise to make efficiencies, offset budgetary pressures and vire monies from elsewhere to fund any such initiatives or costs. Costs are closely monitored.

## Conclusion

14. The Authority is asked to note the financial position as at 30 April 2011.